K083287

510(k) Summary of Safety & Effectiveness **Date: Nov 6, 2008**

FEB - 3 2009

Submitter Name & Address:	Corventis, Inc. 2226 N. First Street San Jose, CA 95131
Contact Person:	Dawn Chang 408-790-9322 (phone) 408-790-9350 (fax)
Trade/Proprietary Name:	AVIVO™
Common/Usual Name:	Mobile Patient Management System
Classification Name:	Arrhythmia Detector and Alarm (21 CFR 870.1025, Product Code DSI) Patient Physiological Monitor (with arrhythmia detection) (21.CFR 870.1025, Product Code MHX)
Class:	Class II, Special Controls

Predicate Devices:

1. CardioNet™ ECG Monitor with Arrhythmia Detection, K072558; DSI, "Arrhythmia Detector and Alarm", 21 CFR 870.1025
2. LifeShirt™ Real-Time, K043604; DQK, "Programmable Diagnostic Computer", 21 CFR 870.1425
3. ZOE™ Fluid Status Monitor, K042113; DSB, "Impedance Plethysmograph", 21 CFR 870.2770
4. SenseWear Armband, 510(k) exempt, IKK, "Isokinetic Testing and Evaluation System", 21 CFR 890.1925

Indication for Use Statement:

The AVIVO Mobile Patient Management System is intended to continuously record, store, and periodically transmit physiological data. The System is indicated for those patients who require monitoring for the detection of non-lethal cardiac arrhythmias. The AVIVO Mobile Patient Management System also monitors, derives and displays:

• ECG

- Heart Rate (including Heart Rate Variability)
- Activity
- Posture
- Body Temperature
- Respiration Rate (including Respiratory Rate Variability)
- Body Fluid Status

Technological Characteristics and Substantial Equivalence

The AVIVIO Mobile Patient Management System includes the following components:

- Adherent Device
- Gateway
- Server

The Adherent Device is a patient-worn device. It collects, stores and transmits user physiological parameters. The Adherent Device, when applied to the user's torso, will automatically activate and measure the above mentioned physiological parameters. Data collected by the sensors are transmitted to the Server for derivation and display via the Gateway periodically. ECG signals recorded by the Adherent Device will be transmitted on a heart rate trigger basis with predetermined thresholds that are not user adjustable. The ECG signals are also transmitted periodically and will be displayed via the Server.

The Gateway receives information from the Adherent Device and transmits them to the Corventis Server. It also interacts with the Corventis Server to receive configuration updates and other relevant hardware diagnostic information.

The Server receives information from the Adherent Device via the Gateway. The secure server performs the following functions:

- Derive physiological parameters using the raw data collected by the Adherent Device.
- Display the physiological parameters in trend graphs format.
- Display ECG waveform when the heart rates are beyond the specified threshold.
- Provide visual notifications when healthcare professionals need to be aware of heart rates that are beyond the specified threshold.
- Provide patient summary reports.

The communication between the Adherent Device and the Gateway is enabled via the BlueTooth™ Technology. The Gateway transmits the data to the Server via cellular technology, where healthcare professionals can access with standard browsers.

Four (4) predicate devices have been identified for the various aspects of the AVIVO Mobile Patient Management System, and AVIVO has the same uses as these predicates. They are:

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1. CardioNet ECG Monitor with Arrhythmia Detection, cleared by FDA under 510(k) number K072558; 21 CFR 870.1025 DSI "Arrhythmia Detector and Alarm"

2. LifeShirt Real-Time, cleared by FDA under 510(k) number K043604; 21 CFR 870.1425 DQK "Programmable Diagnostic Computer"

3. ZOE™ Fluid Status Monitor, cleared by FDA under 510(k) number K042113; 21 CFR 870.2770 DSB "Impedance Plethysmograph"

4. SenseWear Armband, 510(k) exempt, 21 CFR 890.1925 IKK "Isokinetic Testing and Evaluation System"

AVIVO™ Mobile Patient Management Features	**Predicate Devices for Substantial Equivalence**
System Configuration, ECG,	Cardionet™ – K072558
Body Fluid Status	Zoe™ - K042113
Respiratory Rate, Heart Rate, Activity & Posture	LifeShirt™ - K043604
Temperature	SenseWear – 510(k) exempt

Conclusions

The AVIVO Mobile Patient Management System has the same intended use and similar operating principles and technological characteristics as its predicate devices. The same set of safety and performance standards used by the predicates will be applied to the AVIVO Mobile Management Patient Management System. Performance testing conducted on the AVIVO Patient Management System demonstrates that the product performs as it is intended to. Therefore, it is concluded that the AVIVO Patient Management System is as safe and effective as the predicate devices and, thus, is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 3 2009

Corventis, Inc.
Dawn Chang
Senior Regulatory Affairs Associate
2226 N. First Street
San Jose, CA 95131

Re: K083287
Trade/Device Name: AVIVO™ Mobile Patient Management System
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia Detector and Alarm (including ST-segment measurement and alarm)
Regulatory Class: Class II (two)
Product Code: DSI
Dated: January 23, 2009
Received: January 26, 2009

Dear Ms. Chang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with

all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K083287

Indications for Use

510(k) Number (if known): ~~N/A~~ → K083287

Device Name: AVIVO™ Mobile Patient Management System

Indications for Use:

The AVIVO™ Mobile Patient Management System is intended to continuously record, store, and periodically transmit physiological data. The System is indicated for those patients who require monitoring for the detection of non-lethal cardiac arrhythmias. The AVIVO™ Mobile Patient Management System also monitors, derives and displays:

- ECG
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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Kuchner

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K083287